PATENT: AH0948Q

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	)	Examiner: N. Levy
Chung *et al*	)	
	)	Group Art Unit: 1616
Serial No.: 09/431,519	)	
	)	
Filed: November 1, 1999	)	Atty. Docket No.: AH0948Q

For: **IMPROVED GROWTH STIMULANT COMPOSITIONS**

Assistant Commissioner for Patents & Trademarks
Washington, D.C. 20231

#14 Cancel 3-1-02

PRELIMINARY RESPONSE

Sir:

This Preliminary Response is being filed concurrently with the CPA application filed for the above-identified application, and is in response to the Office Action of October 9, 2001. Claims 1-43 were pending in the original application. Claims 21-43 were withdrawn from consideration, and Applicants have preserved the right to file a divisional application for these claims. Claims 1-20 were rejected in the October 9, 2001 Office Action, and are subject of this Continued Prosecution Application.

Rejections under 35 U.S.C. §102 (b)

The Examiner rejected Claims 1-13, 16, 17 and 20 under 35 U.S.C. §102 (b) as being anticipated by Deasy (U.S. Pat. No. 4,874,612). Applicants respectfully traverse this rejection.

The Deasy formulation is a multi-component implant which contains at least two shaped pieces, each containing the active compound. See, for example, Deasy, col. 1, lines 50-61. Deasy requires that each shaped piece of the multi-component implant contain biologically degradable copolymers of lactic acid and glycolic acid with a lactide to glycolide weight ratio of 90:10 to 60:40. See Column 1, lines 50-55 and Claim 1.

In contrast, the present invention is a dual formulation which includes an immediate-release first formulation consisting essentially of an anabolic agent. Deasy does not disclose or suggest a formulation consisting essentially of an anabolic agent.

A rejection under 35 U.S.C. §102 (b) requires that each and every element of a rejected claim be disclosed by the prior art relied upon by the Examiner for making this

rejection. Since Deasy does not have a formulation consisting essentially of an anabolic agent, the present invention is not anticipated by Deasy. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner rejected claims 1-5, and 7-13 under 35 U.S.C. 102(b) as being anticipated by Ivy, (U.S. Pat. No. 4,670,249). Applicants respectfully traverse.

The Ivy formulation is a mixture of a growth-promoting hormone *and* a zearalin. Col. 1, lines 19-21 defines growth-promoting hormones as "polypeptide anabolic hormones.....animals." Zearalins are not peptides and are distinguished from growth-promoting hormones throughout the Ivy patent, e.g. col. 1, line 56- col. 2, line 16; col. 3, lines 61-62.

Ivy differs form the present invention because Ivy does not disclose or suggest an "anabolic implant dual formulation composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release first formulation consisting essentially of an anabolic agent, and (ii) a controlled-release second formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation." Applicants, therefore, respectfully request withdrawal of this 102(b) rejection.

Rejections under 35 U.S.C. §103 (a)

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being unpatentable over Deasy and Porter GB 2397484 in view of Horykiewytsch (U.S. Pat. No. 5,252,561). Applicants respectfully traverse this rejection.

Deasy differs from the present invention since Deasy does not disclose or suggest a formulation consisting essentially of an anabolic agent for the same reasons stated above.

Porter discloses a food supplement bolus for *oral administration*. Porter on page 2 discloses that the supplement is coated with a binding substance and that it is essential that the binding substance be one which dissolves rapidly in the stomach.

The present invention differs from Porter because Porter does not disclose or suggest an anabolic *implant* dual formulation composition. Instead, Porter discloses a *food supplement bolus for oral administration*. The present invention is an implant, not a food supplement bolus. Porter also does not disclose or suggest a formulation consisting essentially of an anabolic agent. Instead, Porter discloses that the food supplement bolus be coated with a binding substance and that it is essential that binding substance be one which

dissolves rapidly in the stomach. Furthermore, Porter differs from the present invention because Porter does not disclose or suggest a dual formulation, an anabolic agent or a controlled release substance as in the present invention.

Hornykiewytsch discloses fused granules for *oral administration* of active substances for ruminants. See Claim 1. Release rate is controlled by surface area of composition. See column 7, lines 8-12.

Hornykiewytsch differs from the present invention in that Hornykiewytsch does not disclose or suggest an anabolic *implant* dual formulation composition. In contrast, Hornykiewytsch discloses compositions for oral administration. Specifically, Hornykiewytsch discloses fused granules for *oral administration* of active substances for ruminants. Furthermore, Hornykiewytsch does not disclose or suggest a dual implant composition which includes an immediate release formulation and a controlled release formulation. Accordingly, neither Porter nor Hornykiewytsch make up for the deficiencies of Deasy.

A rejection under 35 U.S. §103(a) requires that all elements of the rejected claims be disclosed or suggested, either alone or in combination, by the references relied on the Examiner for making this rejection. Since the Deasy, Porter and Horykiewytsch references, either alone or in combination, do not disclose or suggest the present invention, the present invention is not rendered obvious by these references. Accordingly, Applicants respectfuly request reconsideration and withdrawal of this rejection.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious over Lee (U.S. Pat. No. 2,546,759). Applicants respectfully traverse.

Lee discloses a device for subcutaneous administration of medicants. The device is fastened to an animal and the medicant is attached to the device and inserted subcutaneously next to the tissue to be treated. See Column 1, Lines 1-9. Lee's device is geared toward treating chickens.

Lee differs from the present invention wherein Lee does not disclose or suggest an anabolic implant dual formulation composition. In contrast, Lee discloses a device that is attached to an animal for exposing the active substances to tissues of the animal. Furthermore, Lee requires that the active substance always be attached to the device which is fastened to the animal and that the active substance be removed upon removing the device.

Lee also teaches away from implanting compositions subcutaneously in the form of pellets or tablets. In Column 1, lines 27-49, Lee discusses disadvantages of the pellet or tablet implantation technique. In Column 1, Lines 50-56, and Column 2, Lines 1-17, Lee

discusses the advantages of using its implantation device instead of pellet or tablet implantation techniques. Since the present invention is an anabolic implant dual formulation composition which does utilize pellet or tablet implantation techniques (See Page 8, Lines 5-14), Lee teaches away from the present invention.

Since Lee does not disclose or suggest an anabolic implant dual formulation composition, and teaches away from compositions of the present invention which utilize pellet or tablet implantation techniques, Lee does not render the present invention obvious. Applicants, therefore, respectfully request withdrawal of this rejection under 35 U.S.C. §103(a) rejection.

The Examiner rejected Claims 1-20 under 35 U.S.C. §103(a) as being obvious over Deasy, in view of Ivy, O'Callaghan, Sivaramakrishnan and Kim. As explained above, the present invention is not suggested or disclosed in Deasy or Ivy. None of the additional references disclose or suggest an "anabolic implant dual formulation composition for stimulating increased rate of growth, greater amount of growth and greater feed efficiency in cattle, said composition comprising: (i) an immediate-release first formulation consisting essentially of an anabolic agent, and (ii) a controlled-release second formulation comprising an anabolic agent and a controlled-release agent, wherein said immediate-release formulation and said controlled-release formulation cooperate to effect said stimulation." Applicants, therefore, respectfully request withdrawal of this rejection under 35 U.S.C. §103(a).

In summary, the instant invention discloses a dual formulation, only one of which consists essentially of an anabolic agent, and the other which comprises an anabolic agent and a controlled-release agent. None of the references cited by the Examiner, alone or in combination, disclose or suggest the present invention. Applicants, therefore, believe that whether used alone or in combination, the references cited by the Examiner do not anticipate or render the present invention obvious.

There being no other rejection pending, Applicants believe that Claims 1-20 are in condition for allowance, and such action is earnestly requested. If the Examiner has any questions, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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February 11, 2002

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Robert L. Bernstein 2/11/02
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